HAWAII BREAST CANCER COALITION
Diagnostic Standards for Early Breast Cancer
RADIOLOGY

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SCREENING MAMMOGRAPHY GUIDELINES

INTRODUCTION

Periodic mammography screening of asymptomatic women has been shown to reduce breast cancer mortality. Screening mammography is one area in which radiology services can contribute to improve overall patient care. The principles of quality for mammography do not differ basically from those applicable to other radiological examinations. Key points to be considered are the criteria for credentialing professionals, equipment specifications, monitoring and maintenance schedules, standards for image quality, standardized image evaluation procedures, meticulous recordkeeping, and periodic review of data for outcomes of the mammography services.

DEFINITION

Screening mammography is a radiological examination to detect unsuspected breast cancer at an early stage in asymptomatic women. The intent is to separate women into groups with low and high probabilities of breast cancer. This examination may be performed without a physician in attendance. The results may assure most women that no significant abnormalities are detected, while others will be informed that an abnormality exists requiring further investigation.

GOAL

The radiographic goal is to produce the best possible reproducible quality image at the minimal radiation dose necessary to give adequate image information.

INDICATION

Being an asymptomatic woman at least 40 years of age. In women who have hereditary breast cancer syndromes, or are identified as high risk, annual

mammography should be considered starting 5-10 years before the youngest case of breast cancer in the family.

All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation. If the patient is known to be pregnant, the potential radiation risks to the fetus and clinical benefits of the procedure should be considered before proceeding with the study.

Frequency

Asymptomatic women age 40 and older should have an annual screening mammogram.

Self Referral

To maximize utilization of screening, direct access by individuals is permissible without requiring physician referral in advance. Screening facilities which elect to accept such patients must have a well-developed notification procedures for the patient and her physician, or procedures for referral to a qualified physician who has agreed to accept such patients.

QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting Physician

Certification in Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or an equivalent body that certifies in this discipline and is recognized by the American Board of Medical Specialties, may be considered proof of adequate physician qualification. However, the physician's residency and/or fellowship training must include specific criteria for training as outlined below or qualifications may also be fulfilled by those physicians who have completed residency training prior to 1982 and who have interpreted mammography since October 1, 1994.

OR

Two months of full-time documented formal training in the interpretation of mammograms, including instruction in medical radiation physics, radiation effects,

and radiation protection.

In addition, the interpreting physician must:
Interpret mammograms on a regular basis. It is recommended that the physician interpret or review a minimum of 480 mammograms per year.

Regularly participate in mammography continuing education programs. It is recommended that initially, the physician should have 40 hours of CME credits in mammography, and thereafter 15 hours of CME credits in mammography every three years.

Radiological Physicist

Certification by the American Board of Radiology in Radiological Physics or Diagnostic Radiological Physics is recommended.

Radiological Technologist

Certification by the American Registry of Radiological Technologists and/or state licensure is required.

Mammography training in continuing education programs and on-the-job training under the supervision of experienced mammographers.

Must perform mammography on a regular basis.

Must be competent in breast positioning and compression and be knowledgeable concerning technical factors, radiation safety, radiation protection, and quality control.

Should receive continual supervision on image quality from the interpreting physicians.

EQUIPMENT SPECIFICATIONS

Mammography unit:

The mammographic equipment shall be designed especially for mammography and will have a compression device and reciprocating grid.

The equipment specifications must be precise. A low-energy beam is required to produce high subject contrast. Equipment that has Automatic Exposure Control (AEC) is preferable. A properly designed a constructed compression device is essential to further improve contrast, minimize radiographic scatter, produce uniform density, and reduce dose and subject motion. Particular attention must be paid to the X-ray tube. Molybdenum target/molybdenum filter tubes or other combinations developed especially for mammography shall be used for film-screen mammography, whereas tungsten target tubes with added aluminum filtration are best suited for xeroradiography. The focal spot size of the X-ray tube should be 0.6mm nominal or less. 0.3mm is the preferable size for film-screen mammography . The focal-object distance should be 50 cm or more.

A dedicated film processor with developer time and temperature setup specifically for the film being used is preferable for film-screen mammography.

Radiation Dose

The average glandular dose will be measured at least annually. For examination of a 4.5cm thick, compressed breast consisting of 50% glandular and 50% adipose tissue, the dose will be no more than 0.3 rad per exposure for film/screen mammography and no more than 0.4 rad per exposure for xeroradiography.

SPECIFICATION OF EXAMINATION

The examination should ordinarily be limited to craniocaudal and mediolateral oblique views of each breast. On occasion, supplementary views may be required to visualize breast tissue optimally, but such views should not be done routinely. Where pathology is suspected, a recommendation for additional imaging studies, diagnostic mammography, or biopsy may be warranted.

If a breast physical examination is not available at the screening site, women should be informed that physical examination is a complementary and necessary procedure.

Comparison with prior mammograms

Prior mammograms should be obtained when practical.

Film Labeling

Adequate documentation of the study is essential for high quality patient care. All

radiographic images should be labeled in accordance with the current ACR Mammography Quality Control Manual. Film labeling should include an identification label containing:

Facility name and location
Patient's first and last names
Unique identification number and/or date of birth
Examination date
Technologist's initials (or identification number)
Cassette (screen) number

The film should also include a radiopaque marker placed on the film near the axilla for identification of laterality and view.

Viewing Conditions

Viewboxes

Viewboxes should provide a relatively high luminance level. This is generally higher than that required for viewing conventional radiographs. It is essential to mask the area around the mammograms to exclude extraneous light which reduces image contrast and limits maximum densities that can be seen without "bright-lighting" each film. All viewboxes should be checked periodically to assure that they are in optimal condition.

Viewing conditions

Contrast is extremely important in the mammographic image and is degraded by extraneous light. Viewboxes should be positioned to avoid light from windows, other viewboxes, and other sources of bright light, either direct or reflected. General lighting should be at a low level and diffuse.

Film Retention

Original mammograms shall be retained by a facility or made available to the patient for a period of five (5) years. State law or federal acts may require a longer retention period.

Free Standing and Mobile Settings

Screening mammography may take place in non-traditional radiology settings where there may not be a physician in attendance. The mammography offered must follow all of the previously mentioned guidelines with strict adherence to

documented protocols.

DOCUMENTATION (REPORTING)

A definitive diagnosis is not usually rendered, although in some instances a highly suspicious abnormality may be identified which will warrant a recommendation for biopsy. More commonly, those in the high-probability group will be recalled for further diagnostic studies. Reporting should be in accordance with the ACR Standard for Communication.

Description of abnormalities detected by screening and recommendations for subsequent follow-up studies should be included in the report.

Follow-up diagnostic imaging studies should be done under the direct on-site supervision of a qualified mammography physician.

The report should be rendered as soon as reasonably possible.

All reports in the categories of suspicious abnormality or highly suggestive of malignancy should be communicated to the referring physician or his/her designated representative in a manner that assures receipt and documentation of the report, such as by telephone, fax, or certified mail.

Self-referred (i.e. those women who have no referring physician) patients should be notified of the results of the screening study by mail. Reports in the categories of probably benign - short interval follow-up, suspicious abnormality, or highly suggestive of malignancy should be communicated to the patient in a manner that assures receipt and documentation of the report, such as by telephone, fax, or certified mail. The report should indicate a need for further consultation with a physician, and a follow-up contact with the patient should be made to determine that she has consulted a physician for follow-up care.

QUALITY CONTROL PROGRAM

A documented quality control program with procedure manuals and logs will be maintained and be in compliance with the ACR Quality Control Manual for mammography. This includes the following checks:

TECHNOLOGIST'S CHECKS

Darkroom Cleanliness
Processor Quality Control
Screen Cleanliness

Viewboxes and Viewing Conditions
Phantom Images
Visual Check List
Repeat Analysis
Analysis of Fixer Retention in Film
Darkroom Fog
Screen-Film Contact
Compression

PHYSICIST'S CHECKS

Cassette Holder Assembly and Equipment Evaluation
Collimation Assessment
Focal Spot Size Measurement
kVp Accuracy/Reproducibility
Beam Quality Assessment (Half-Value Layer Measurement)
Automatic Exposure Control (AEC) System Performance Assessment
Screen Uniformity
Breast Entrance Exposure and Average Glandular (Breast) Dose
Artifact Evaluation

Accreditation by the ACR Mammography Accreditation Program would document compliance with the recommendations in this section.

PROFESSIONAL QUALITY IMPROVEMENT PROGRAM

Systems for reviewing outcome data from mammography screening will be established. Included will be follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports. It is understood that in some practice situations it will not be possible to obtain follow-up information on all positive mammograms.

REFERENCES

American College of Radiology Standards 1997 , "ACR Standard for the Performance of Screening Mammography", pp. 43-47.

DIAGNOSTIC MAMMOGRAPHY AND PROBLEM SOLVING BREAST EVALUATIONS

INTRODUCTION

Unlike screening mammography, which is intended to detect unsuspected breast cancer, problem-solving breast evaluation (diagnostic mammography and appropriate supplemental procedures) is intended to provide specific analytic evaluation of patients with clinically detected or screening- detected abnormalities. The diagnostic breast evaluation should lead to definitive conclusions about the patient's symptoms or findings to enable specific management recommendations.

DEFINITION

The request for problem-solving breast evaluation is a consultation that will result in a comprehensive imaging examination. In addition to the standard craniocaudal (CC) and mediolateral oblique (MLO) views, a diagnostic mammogram may include additional views and may be supplemented by other procedures, such as sonography, ductography, fine-needle aspiration, large core needle biopsy, or MRI, to complete the diagnostic assessment. Diagnostic breast evaluation is performed under the direct, on-site supervision of an interpreting physician qualified in mammography.

The patient history, symptoms and signs, such as breast mass, nipple discharge, pain, or dimpling the skin; findings on physical examination; and results of prior screening mammography, if preformed, will focus the diagnostic breast evaluation.

GOAL

The goal of diagnostic breast evaluation is to provide definitive information for patients who are symptomatic, have physical findings, or have areas of radiographic concern. Information gained from comprehensive problem-solving breast evaluation should lead to specific interpretive conclusions and/or further management recommendations.

COMMENTS

The above American College of Radiology Practice Standards describes an integrated and comprehensive method of patient evaluation, which provides an improved standard of patient care. As breast imaging and percutaneous diagnosis methods have evolved in recent years, the number of diagnostic options have increased in number and become more complex, which makes it difficult for the referring clinician to predict in advance which breast imaging tests would be most appropriate. The mammographer is able to determine the appropriate sequence of evaluation in a timely and cost effective manner often completing the diagnostic

evaluation in one, or occasionally two visits. This spares the patient and referring clinician the burden of scheduling different breast examinations on multiple days, frequently with different radiologists, and results in improved patient compliance. The use of comprehensive breast problem solving evaluations is encouraged, because it provides better patient care. Patients who are forced to undergo prolonged evaluations frequently become dissatisfied and may discontinue the workup, and be lost to follow-up. This can result in serious consequences for the patient because of delayed diagnosis, and increases the medico-legal risk to health care providers. Further, prolonged workups may discourage the patient from routine breast screening in the future.

Most diagnostic breast evaluations can be completed with the use of diagnostic mammography and/or breast ultrasound. In younger patients, who are less than 35 to 30 years old, breast ultrasound will be the most useful initial examination of choice. In general, mammography is less helpful in younger patients because the usually denser mammary parenchyma in this age group may obscure a lesion. In a small number of patients, additional imaging examination such as ductography, scintimammography and breast MRI may be needed to obtain important information that mammography and/or ultrasound alone cannot provide.

It should be emphasized that diagnostic imaging evaluation is a complement to physical examination of the breast, NOT a replacement. This is because a small number of palpable cancers will be occult or poorly demonstrated on breast imaging studies. All patients deserve a careful and thorough breast physical examination by an experienced physician or nurse practitioner prior to the breast imaging evaluation. When indicated clinically, or when desired by the patient, surgical consultation is encouraged.

PATIENT SELECTION

Women in the following circumstances should be evaluated with diagnostic breast imaging studies as defined above and should not be considered candidates for screening mammography. The following list may not be comprehensive, and there may be additional indications for problem solving breast imaging.

Specific focus of clinical concern such as mass, nipple discharge, skin changes, or persistent focal area of pain.

Comment: nipple discharge that is not spontaneous or that is expressed from many ducts bilaterally may not reflect pathology that requires diagnostic evaluation, and women with this finding may be candidates for screening mammography. Similarly, greenish nipple discharges are usually not of clinical significance. Possible radiographic abnormalities detected on screening mammography.

Personal history of breast cancer

After breast conservation therapy for carcinoma
In follow-up of the remaining breast after treatment of breast cancer with mastectomy diagnostic mammography may be preferred.

Short interval follow-up (e.g. Less than one year) for clinical or radiographic concerns.

Augmented breast (silicone or saline implants).

Any patient requiring direct involvement of the radiologist for specialized views, sonography, physical examination, or consultation.

INDICATIONS AND UTILIZATION OF DIAGNOSTIC BREAST IMAGING EXAMINATIONS

DIAGNOSTIC MAMMOGRAPHY

Mammography is the only breast imaging technique, which can reliably detect the microcalcifications, which are associated with about half of all breast cancers. Mammography is also able to define the margins of many breast masses. Mammography is most sensitive when patients have breasts that are largely of fat density. Mammography cannot differentiate between solid and cystic masses, and may be insensitive to masses when the breast tissues are mammographically dense (largely of water density). Certain breast lesions may be positioned too posteriorly or marginally to be included in standard CC and MLO mammographic views. In general diagnostic mammography is the initial test diagnostic test of choice in women over age 35, and often is the only examination needed to evaluate a finding on screening mammography.

BREAST ULTRASOUND

Breast ultrasound is the initial imaging test of choice to evaluate masses in younger women, especially under age 30, and in lactating and pregnant patients. Breast ultrasound should be considered part of a diagnostic breast evaluation of palpable or ambiguous mammographic masses or focal asymmetric densities, which may represent or mask a mass. The breast ultrasound should be directly correlated to the area of concern on the mammogram or physical examination. If a palpable mass is present its location should be clearly discussed or the general area diagramed on the clinical request for the examination. Ultrasound is not a screening study to detect occult breast masses, and it is not a standard technique to search for microcalcifications. Ultrasound is an excellent method to diagnosis breast cyst. Ultrasound is also helpful in reinforcing the clinical impression that a

palpable lump is benign, especially if the ultrasound demonstrates typically benign ultrasonic findings, such as cysts, intramammary lymph nodes, well circumscribed fibroadenomas, or echogenic ridges of benign appearing fibroglandular tissue which directly corresponds with the area of palpable concern. Breast Ultrasound is able to detect many mammographically occult cancers and has been reported to detect almost 90% of invasive lobular carcinomas which are typically difficult to visualize on mammograpghy. If the clinical examination is suspicious for malignancy, then further evaluation with surgical consultation and /or FNA to complete the triple test may be indicated, as some diffusely infiltrative carcinomas are occult on ultrasound.

BREAST MRI

MRI of the breast is the most sensitive imaging examination for invasive breast carcinoma with the possible exception of PET. Multiple studies have shown that the sensitivity of MRI for invasive breast carcinoma is 96%-100%. The test is less sensitive for the detection of DCIS. In recent years, the specificity of MRI for breast carcinoma has improved to about 85%, in comparison to the specificity rate of mammography, which is about 25%. MRI is useful in a small minority of problematic patients undergoing diagnostic breast evaluation. It also has proven utility as a cost-effective method of preoperatively staging breast carcinoma as it is more accurate than mammography in estimating the size of the primary tumor and excluding the presence of multi-focal and multi-quadrant carcinoma. MRI is a FDA approved modality, and is an accepted practice standard of breast imaging for the American College of Radiology.

SCINTIMAMMOGRAPHY

Scintimammography is a FDA accepted examination, which has been shown to be about 85%-95% sensitive to the detection of palpable breast carcinomas. Scintimammography is useful for the evaluation of masses which measure at least one to two centimeters in size, with smaller lesions usually being below it's level of resolution. The positive predictive value for palpable breast cancer for scintimammography is about 88%. Scintimammography and MRI have also been shown to have greater utility than mammography in assessing preoperative neoadjuvant chemotherapy.

REPORTING FORMAT AND TERMINOLOGY FOR BREAST IMAGING REPORTS

Data to Include:

size of lesion
location (quadrant and relationship to areolar complex)
relative depth from skin surface
additional lesions and /or calcifications that may be present
recommendations for biopsy and/ or follow-up

Breast Imaging reporting and data system (Bi-Rads) reporting categories

The American College of Radiology BI-RADS system has been developed in cooperation with the American Medical Society, American College of Surgery and the American College of Pathology. Use of ACR Bi-Rad system is mandatory for mammography and it may be used for all breast-imaging examinations. The use of Bi-Rads terminology for describing breast-imaging findings are strongly recommended.

Category 0 *	**Need Additional Imaging Evaluation:**
Category 1*	**Negative**
Category 2*	**Benign Findings**
Category 3*	**Probably Benign Finding- Short interval follow-up suggested**
Category 4*	**Suspicious Abnormality- Biopsy should be considered**
Category 5*	**Highly suggestive of malignancy - Appropriate action should be taken**

LOCAL AND REGIONAL STAGING OF BREAST CANCER FOR SURGICAL MANAGEMENT

The principles of oncological surgery include detection of carcinoma, the determination of size and location of the primary tumor, exclusion of secondary tumors or satellite lesions, and the assessment of regional and distant metastatic disease. Current advances in breast imaging are now available to more accurately provide this information in many patients. In-patients with fat density breast tissue, mammography is usually quite adequate to assess the extent of the tumor within the breast. Many patients however, have heterogeneously dense or very dense mammary parenchyma, which limits the ability of mammography to locally stage breast carcinoma accurately. Breast imaging and percutaneous diagnostic procedures can be used to assist in pre-operative planning, in order to achieve clear surgical margins, and decrease the number of operative re-incisions. One or more of the following options may be helpful in oncological patient management:

The use of percutaneous biopsy has been shown to significantly increase the chance of resecting malignant breast disease in a single operative procedure. When a lesion is felt to be highly suspicious for malignancy, preoperative FNA of palpable lesions and/or image-guided biopsy of non-palpable lesions should be considered to confirm the diagnosis of cancer prior to open surgery. If a percutaneous biopsy of a highly suspicious lesion is negative, then open diagnostic surgical biopsy should still be strongly considered.

If mammography is felt to be insufficient to accurately determine the extent of a breast carcinoma, then further preoperative breast imaging may be warranted in order to stage the primary tumor, and exclude multifocal and multiquadrant. Breast imaging examinations, which have been shown to have clinical utility for this indication, include breast MRI and PET scanning.

Preoperative or peri-operative staging of the regional lymph nodes by appropriate imaging techniques may be clinically desired in order to exclude regional nodal metastatic disease. This information may be helpful in selecting or excluding patients for standard axillary nodal dissection. Breast imaging procedures with utility for this indication include sentinel node imaging and PET.

POST LUMPECTOMY IMAGING

Breast conservation surgery has proven to be a major advance in the treatment of breast cancer. The possibility of local recurrence of carcinoma in the treated breast exists however, so close surveillance is advisable. The most cost-effective component of post lumpectomy follow-up is serial physical examination by a physician, and monthly self-breast examination by the patient. Mammography is the routine imaging test of choice for postoperative imaging. Mammography is most helpful if a post operative baseline examination is obtained and if patients are initially followed closely mammographically at six to twelve month intervals. Postoperative fibrosis may develop and progress for up to six months post surgery, and if radiation therapy is used progressive scarring and fibrosis can be seen for up to eighteen months. These changes can closely resemble the appearance of recurrent carcinoma in some patients. For this reason about half the time local recurrent breast carcinoma is detected on the physical examination before it is appreciated on the mammography. Imaging techniques like MRI, scintimammography and PET are more sensitive and specific for recurrent carcinoma, especially in mammographically dense breasts. When clinically indicated, these techniques can help defer surgical reexcisions or biopsy in patients with worrisome but benign mammographic changes. MRI in the immediate postoperative period may also be a cost-effective procedure if the surgical margins are positive. In this clinical setting MRI can provide useful information about the location and size of the residual tumor. Such information may allow the surgeon to better select whether a wider re-excision or mastectomy is the more appropriate approach.

SPECIMEN IMAGING

INTRODUCTION

Specimen imaging after surgical excision of nonpalpable, mammographically or ultrasonically identified lesions has become the standard of practice. Even if the surgeon feels confident that the lesion has been excised, specimen imaging by radiography or ultrasound should be performed for documentation. Specimen imaging should be performed on all breast lesions which are surgically excised after wire localization.

GUIDELINES

Specimen imaging should be evaluated while the patient is still in the operating room, and compared to the preoperative mammogram or ultrasound, to determine adequacy of excision. Documenting the presence of the lesion within the surgical specimen ensures that the area of concern has been adequately sampled. This method provides validation of both lesion excision and localization wire removal, and also assists the pathologist in identifying the lesion within the excised tissue.

For radiography the specimen is ideally compressed in a gridbox with an alpha-numeric grid system and radiographed with low kVp technique and magnification. The radiopaque grid allows identification of the position of the lesion within the specimen, and the coordinates are given to the pathologist for more careful sectioning of the tissue. Magnification radiography of the specimen is preferable because it can improve the visualization of calcifications. Compression of the specimen permits the visualization of masses as well as calcifications in the tissue samples. The radiologist should immediately inform the surgeon about whether or not the lesion is perceived on the specimen radiograph and the relationship of the lesion to the tissue margins. The surgeon may then perform a wider excision when necessary. For some vague soft-tissue densities, the specimen radiograph may be ambiguous. Turning the specimen 90 degrees and repeating the radiograph may help visualize some lesions. Alternatively digital specimen radiography can be used which is faster and can be optimized with magnification or filtering techniques.

Comment
An alternative to the gridbox specimen container is a plastic bag that can be sealed to facilitate handling. Some have found that marking the location of the lesion within the specimen with additional needles aids the pathologist in ensuring the lesion that was of concern is actually evaluated. The radiologist should consult with the pathologist to come to an agreement in specimen handling in their particular

medical center.

Two specimen radiographs should be routinely obtained. One is retained for the imaging record; the second accompanies the tissue to the pathology department to alert the pathologist as to the lesion that was targeted.

ULTRASOUND SPECIMEN IMAGING

Lesions that are not visible on the mammogram and are localized using ultrasound may not be visible using specimen radiography. By placing the specimen in a plastic bag the tissue can be evaluated using ultrasound while still in the bag by applying coupling gel to the surface of the bag.

PARAFFIN BLOCK RADIOGRAPHY

When the target lesion is calcifications that were present on the specimen radiograph but not found at pathologic analysis of the biopsy sections, radiography of the tissue specimens placed in paraffin block may guide the pathologist in identifying the calcifications. Sometimes imaging the block by turning it on its side can demonstrate that suspicious calcifications are deep in the block and that levels through the block should be obtained.

FOLLOW-UP WHEN SPECIMEN IMAGING IS EQUIVOCAL

When additional excision is not possible, or when specimen imaging or pathology remains equivocal, postoperative mammography or ultrasound of the breast is recommended to evaluate for lesion removal. Follow-up should be performed as soon as the patient can tolerate the examination. If the lesion is still present at that time, plans for re-excision can be made. In patients with ductal carcinoma in situ specimen imaging is often not adequate to determine the completeness of excision. In these patients a post-operative mammogram should be considered to document complete removal of the mammographic abnormality.

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GUIDELINES FOR THE PERFORMANCE OF
NEEDLE LOCALIZED BREAST BIOPSY

INTRODUCTION

Needle localized breast biopsy was first introduced in 1965 (1) and has become one of the standard methods in arriving at a histologic diagnosis of nonpalpable mammographically detected breast lesions. Needle placement for preoperative localization can be accomplished using standard mammography with or without stereotactic guidance or ultrasound.

High quality breast imaging is necessary to establish the need for biopsy and to accurately guide the placement of localization instruments. Prior to the performance of needle localization biopsy, the lesion should be completely evaluated with the problem solving breast evaluation which may include diagnostic mammography, ultrasound , CT and MRI.

GUIDELINES

Percutaneous preoperative localizations are procedures performed to direct the surgeon to the area(s) of radiographic concern so that the lesion(s) can be excised successfully. There are a variety of systems for preoperative localization including mammographic or ultrasound-guided placement of a needle into or near the lesion. Wireless localization by such methods as the use of dye or sterile carbon are an acceptable alternative. When the position of the needle has been confirmed, a hooked wire can be advanced through the needle and left in position and/or a small amount of dye injected to mark the site for the surgeon. The most common technique for nonstereotactic needle insertion is placing the needle parallel to the chest wall with the breast under firm compression using a fenestrated paddle. Usually, there is a coordinate system marked on the paddle. Alternatively, a needle can be place in the AP direction, perpendicular to the chest wall, with the patient not in compression. This is accomplished by extrapolating measurements taken from compressed mammograms to the uncompressed breast and is very operator dependent. Typical needles for needle localized breast biopsy include the Hawkins 1 needle, the Homer Mammolock Plus and the Kopans needle, among others.

Lesion localization is typically done in an outpatient facility with local anesthesia such as Lidocaine or Sensorcaine with or without epinepherine. In certain highly anxious patients, premedication with oral Vallium is sometimes used and/or inhaled nitrous oxide. Post needle insertion imaging is essential usually cranial caudal and either medial lateral or lateral medial and these images should be sent with the surgeon so that he/she has the benefit of seeing them prior to performing the

excisional biopsy. If the needle is inserted on ultrasound guidance, then two orthogonal ultrasound images should be obtained. CC and ML mammograms with the wire in place can also be very useful for the surgeon not used to looking at ultrasound images, provided the lesion is mammographically visable.

In any of the preoperative localization procedures a specimen radiograph, or ultrasound, to confirm that the lesion localized preoperatively is contained within the specimen is essential (please see the specimen imaging guidelines).

COMMENT

Although the most common needle localization breast biopsy technique is performed parallel to the chest wall with the breast and lesion held firmly in compression, a recent review of over 40 studies demonstrated no clear-cut evidence of any single standard or most accurate localization technique (2).

INDICATIONS/CONTRAINDICATIONS

There are no absolute contraindications to preoperative localization procedures. Prior to the procedure, the patient should be asked about allergies, use of medications such as aspirin or anticoagulants or history of bleeding, diatheses. As with all interventional procedures, the procedure should be fully described and the relative risks, benefits, limitations and alternatives should be explained to the patient. Pre-surgical localization may be used to localize lesions prior to procedures:

I. If surgical excision is planned;
2. If a previously sampled lesion receives histopathologically based recommendation for complete excision;
3. If there is discordance between the mammographic or US-based level of suspicion and the pathologic findings on core needle biopsy.

QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

(See Guidelines for Performance of Stereotactically Guided Breast Interventional Procedures)

EQUIPMENT SPECIFICATIONS

(See Guidelines for Performance of Stereotactically Guided Breast Interventional Procedures and Performance of Screening & Diagnostic Mammography)

QUALITY CONTROL

(See Guidelines for Performance of Stereotactically Guided Breast Interventional Procedures and Performance of Screening & Diagnostic Mammography)

DOCUMENTATION

(See Guidelines for Performance of Stereotactically Guided Breast Interventional Procedures and Performance of Screening & Diagnostic Mammography)

As noted, it is essential that all pathology results be reported to the radiologist performing the preoperative localization procedure.

QUALITY IMPROVEMENT

(See Guidelines for Performance of Stereotactically Guided Breast Interventional Procedures and Performance of Screening & Diagnostic Mammography)

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1. Dodd GD, et al. The radiologic diagnosis of cancer. In: Nealon TF JR, ed. Management of the patient with cancer. Philadelphia, PA: Sauders 1965;88.

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GUIDELINES FOR PERFORMANCE OF STEREOTACTICALLY GUIDED BREAST INTERVENTIONAL PROCEDURES

INTRODUCTION

Many mammographically detected breast lesions require tissue sampling for diagnosis. The great majority of both nonpalpable (and palpable lesions) are amenable to percutaneous biopsy. Excisional biopsy following needle localization has been the traditional approach for nonpalpable solid lesions. Currently stereotactically guided and ultrasonographically guided fine-needle aspiration (FNA) and core needle biopsy (CNB) are the most common methods in the U.S. and Europe for the biopsy of nonpalpable lesions as well as for some palpable lesions (Ultrasonically guided procedures are discussed in a separate standard.) Accurate needle placement for preoperative localizations or lesion sampling can be directed using standard mammography with or without stereotactic guidance or with ultrasound (US).

High-quality breast imaging evaluation is necessary to establish the need for biopsy and to accurately guide placement of localization and/or biopsy instruments. The accuracy of stereotaxic biopsy has been shown rival that of open surgical excision when expert hands perform the procedure. Radiologists who perform image guided breast biopsies must adhere to the rigorous practice guidelines of the American College of Radiology in order to achieve these results. Newer percutaneous techniques such as mammotomy also decrease the chance of sampling error because the majority of lesions less than one centimeter are completely removed by this procedure. Needle sampling procedures should not be used to replace appropriate breast-imaging evaluations.

Factors contributing to optimal patient care include personnel qualifications and credentialing, patient selection, equipment specifications, record keeping, patient follow-up data, and periodic reviews of outcome data.

DEFINITION

Stereotactically-guided percutaneous pre-operative localizations are procedures performed to direct the surgeon to the area(s) of radiographic concern so that the lesion(s) can be excised successfully.

Stereotactically-guided percutaneous FNA is performed to obtain cellular aspirates from mammographically detected breast lesions.

Stereotactically-guided CNB is performed to provide tissue cores from mammographically detected breast lesions. Two different types of large gauge (11g or 14g) needles can be used, automated true cut needles or vacuum-assisted directable needles (Biopsys) and a minimum of 5 14g samples should be obtained. Both upright and prone tables are currently in use. Vaccum-Assisted stereotaxic biopsy is an acceptable alternative to core needle technique and typically yields larger specimens, which decreases the chance of sampling error. Specimen x-ray is essential for biopsy of microcalcifications and is often useful for non-calcified lesions as well.

GOALS

The goal of pre-operative, stereotactically-guided lesion localization is to facilitate the accurate and successful excision of breast lesions detected by imaging procedures.

The goals of image-guided FNA or CNB are to establish the diagnosis of suspicious (Breast imaging Reporting and Data System, BI-RADS™ Category 4 and 5) breast lesions seen on mammograms and to facilitate biopsy of probably benign (BI-RADS™ Category 3) lesions which the patient and/or clinician is uncomfortable following over time.

Successful utilization of this technology requires high quality imaging, expertise in lesion characterization and patient selection, accurate positioning of the needle for biopsy, proper use of local anesthesia, removal of adequate tissue for analysis, and ongoing assessment of concordance between the imaging and pathologic findings. Correlation of the pathologic findings with imaging characteristics is essential for every case.

INDICATIONS/CONTRAINDICATIONS

Primary diagnosis

Percutaneous tissue sampling can be performed for:

1. A lesion that is thought to be highly suggestive of malignancy (BI-RADS™ Category 5), to confirm the diagnosis so that definitive treatment options can be selected in advance.

2. Multiple suspicious or indeterminate lesions, particularly in a multicentric distribution (two or more different quadrants), to facilitate treatment planning.

3. Suspicious lesions (BI-RADS™ Category 4).

4. Probably benign lesions (BI-RADS™ Category 3) where patient anxiety is

high or the procedure is requested for confirmation.

Confirmation of findings

Lesions where the initial FNA or CNB procedure or the surgical biopsy has provided insufficient material for analysis. Alternatives for repeat biopsy are percutaneous sampling or surgical excision. Presurgical localizations

Standard mammographic or stereotactic localization may be used to localize lesions prior to surgical procedures:

1. If surgical excision is planned

2. If a previously sampled lesion receives a histopathologically based recommendation for complete excision (such as with the finding of atypical hyperplasia).

3. If there is discordance between the mammographic or the US-based level of suspicion and the histopathologic interpretation of a previously sampled lesion.

There are no absolute contraindications to percutaneous procedures. Prior to the procedure, the patient should be asked about allergies, use of medications such as aspirin or anticoagulants, or a history of bleeding diatheses. As with all interventional procedures, the procedure should be fully described and the relative risks, benefits, limitations, an alternatives should be explained to the patient.

QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

lnterpretative experience in screening and diagnostic mammography is essential for those performing stereotactically-guided FNA or CNB. Physicians, physicists, and radiologic technologists should meet the following qualifications from the ACR Standards for Screening Mammography and Diagnostic Mammography and Problem-Solving Breast Evaluation. Prior to the stereotactic procedure, the physician should be able to identify the significant lesion(s) on mammography so that the correct area of the breast is localized or biopsied. This is particularly important when small field-of-view imaging equipment is employed. Technologists and physicists need specialized skills to optimize their participation in the procedure.

General Qualifications

Physician

a. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or an equivalent body that certifies in this discipline and is recognized by the American Board of Medical Specialties may be considered proof of adequate physician qualification. The physician's residency and/or fellowship training must include specific criteria for training as outlined in A.1b or qualifications may also be fulfilled by those physicians who completed residency training prior to 1982 and who have interpreted mammography since October 1, 1994.

OR

Two months of full-time documented formal training in the interpretation of mammograms, including instruction in medical radiation physics, radiation effects, and radiation protection.

b. In addition, the physician must:

Interpret on a regular basis. It is recommended and that the physician interpret or review a minimum of 480 mammograms per year.

AND

Participate regularly in mammography continuing education programs. It is recommended that the physician should have continuing education in accordance with MQSA (currently, 40 hours of continuing medical education (CME) credits in mammography initially, and thereafter 15 hours of CME credits in mammography every three years).

Radiological Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology considers that certification and continuing education in the appropriate subfield(s) demonstrate that an individual is competent to practice one or more of the subfields in medical physics, and to be a Qualified Medical Physicist, The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR).

The subfields of medical physics are Therapeutic Radiological Physics, Diagnostic Radiological Physics, Medical Nuclear Physics, and Radiological Physics.

A qualified medical physicist should be in accordance with the ACR Standard for

Continuing Medical Education (CME).

Radiological Technologist

a. Certification by the American Registry of Radiological Technologists and/or state licensure is required.

b. Mammography training in continuing education programs and on-the-job training under the supervision of experienced mammographers.

c. Performance of mammography on a regular basis.

d. Competence in breast positioning and compression and knowledge of technical factors, radiation safety, radiation protection, and quality control.

e. Continual supervision on image quality from the interpreting physicians.

Radiographic equipment used for this procedure should be operated by a radiologic technologist or a physician who meets the qualifications as outlined above.

Specific Qualifications

In addition to the qualification requirements stated above for personnel performing mammography, the following specific qualifications for personnel participating in stereotactic biopsy are recommended:

Physician

Three hours of Category I CME didactic instruction in stereotactic biopsy initially. Completion of a residency program which includes instruction in stereotactic breast needle procedures is also acceptable. Additionally, documentation of three hands-on procedures under the guidance of a qualified physician or the manufacturer's application specialist. There should be documentation of the performance of an average of at least 12 stereotactic biopsies per year.

Radiologic Technologist

Initially, three hours of Category A (continuing education unit) CEU in stereotactic biopsy plus documentation of five hands-on procedures under the guidance of a qualified technologist or the manufacturer's application specialist. There should be

documentation of the performance of an average of at least 12 stereotactic biopsies per year.

Physicists

Three hours of continuing education in stereotactic biopsy unit physics as well as documentation of physics surveys of at least 2 units or hands-on training under the guidance of a qualified medical physicist.

EQUIPMENT SPECIFICATIONS

Radiographic equipment that can be used for stereotactically-guided percutaneous breast interventional procedures includes prone stereotactic units and add-on stereotactic devices for dedicated mammographic units.
Calibration of the equipment should be undertaken by the manufacturer at the time of installation. Verification of calibration and acceptance testing should be completed by the medical physicist before use.

QUALITY CONTROL

A documented quality control program for stereotactically-guided pre-operative localizations, FNAs and CNBs with procedure manuals and records should be maintained. The Quality Improvement/Quality Control Program should include regular meetings of the entire team including the radiologist, technologist, and medical physicist.

Technologist's CHECKS:

1. **Zero alignment test - before use each day**
2. **Localization accuracy - before use each day**
3. **Visual checklist - weekly**
4. **Phantom image test - weekly**
5. **Compression force test - semiannually**
6. **Film processor quality control - daily (if film is used)**

Physicist's CHECKS:

All parameters that are available must be tested.

1. **Mammographic Unit Assembly (with appropriate modifications)**
2. **Evaluation of focal spot performance**
3. **kVp Accuracy /Reproducibility**
4. **Beam Quality Assessment (Half-Value Layer Measurement)**
5. **Automatic Exposure Control (AEC) System Performance Assessment**
6. **Breast Entrance Exposure, Average Glandular Dose, and AEC Reproducibility**
7. **Image Quality Evaluation**
8. **Artifact Evaluation**
9. **Digital Field Uniformity test**
10. **Localization accuracy**
11. **Zero alignment**

DOCUMENTATION

Documentation of stereotactically-guided FNA, CNB, or pre-operative localization should be maintained. Images showing needle position should be recorded on a retrievable and reviewable image storage format such as film, videotape, or computerized images stored on optical disc.

A. Image labeling should include permanent identification containing:

1. **Facility name and location**
2. **Examination date**
3. **Patient's first and last names**
4. **Identification number and/or date of birth**
5. **Technologist’s identification number or initials**

B. The physician's report of imaging-guided needle procedures of the breast should include:

1. **Procedure performed**
2. **Local anesthesia, if used, and amount**
3. **Immediate complications and required treatment, if any**
4. **Specimen radiographs, if performed, and results of specimen radiography, if obtained**

C. Follow-up documentation should include:

1. **Pathology results**
2. **Patient disposition based on biopsy results and imaging information**
3. **Delayed complications and required treatment, if any.**

D. **Retention of the procedure images including specimen radiographs should be consistent with the policies for retention of mammograms, in compliance with federal and state regulations, with local health care facility procedures, and with clinical need.**

Reporting should be in accordance with the ACR Standard for Communication.

The physician performing the procedure should be responsible for obtaining results of the cytologic or histologic sampling, and these results should be communicated to the referring physician or to the patient, as appropriate. These communications should be documented.

QUALITY IMPROVEMENT

Ongoing medical audits of stereotactically-guided preoperative localization, FNA, and CNB programs should be performed. As a minimum the physician should be able to provide the number of procedures done by type, the number of cancers diagnosed, and the number of complications requiring treatment.

The number of and the indication (i.e., inconclusive result, inadequate sample, ductal hyperplasia with atypia, complex sclerosing lesions/radial scar, lesion requiring more tissue for accurate diagnosis or technical failure, etc.) for repeat biopsies and excisional biopsies recommended following stereotactically-guided FNA or CNB should be tracked.

The rate of compliance with recommended follow-up in women with benign results following stereotactically-guided FNA or CNB should be tracked. Follow-up of all biopsies should be pursued to detect and record any false-negative or false-positive results.

References:

Parker, SH, Burbank F, Jackman RJ, et al. Percutaneous large-core breast biopsy: A multi-institutional study. Radiology 1995; 193:359-364.

American College of Radiology Standards, 1997

GUIDELINES FOR THE PERFORMANCE OF ULTRASOUND-GUIDED PERCUTANEOUS BREAST INTERVENTIONAL PROCEDURES

I. INTRODUCTION

Breast interventional procedures may be diagnostic, such as tissue sampling, or therapeutic, such as abscess drainage, or both diagnostic and therapeutic, such as cyst aspiration. These include, but are not limited to: cyst aspiration, abscess drainage, presurgical needle localization, fine needle aspiration (FNA) biopsy, large core needle biopsy (CNB), and galactography using ultrasound (US) to guide entry into a dilated duct.

US is one of several imaging techniques that may be used to guide interventional procedures. Other breast imaging modalities include conventional or digital mammography, CT, and MRI.

II. GENERAL PRINCIPLES

For nonpalpable lesions detected mammographically (and occasionally, by other imaging techniques), a recommendation for performing a percutaneous breast procedure is based upon high-quality breast imaging assessed by a physician qualified to render an interpretation of these images (see Section IV below).

The management of palpable breast masses, which often involves percutaneous procedures, and other symptoms of breast disorders, relies on clinical evaluation in conjunction with appropriate imaging studies that may include diagnostic mammography (see ACR Standard for Diagnostic Mammography and Problem-Solving Breast Evaluation) and/or breast US (see ACR Standard for Performing of the Breast Ultrasound Examination).

Prior to the performance of any US-guided percutaneous procedure, the lesion should be evaluated completely with US which meets the guidelines of the ACR Standard for Performing of the Breast Ultrasound Examination.

Successful utilization of US to guide breast interventional procedures relies on high-quality imaging, expertise in lesion characterization and patient selection, experience in US-guided techniques for accurate positioning of the sampling or localization device, and effective methods of obtaining tissue for analysis. The imaging and the cyto- or histopathologic interpretations should be concordant, and records should be kept to document results and patient management recommendations.

When a lesion is identified and characterized using US, this imaging technique may be selected for interventional guidance because of operator experience, patient comfort, efficiency, economy, or sampling accuracy (real-time visualization of the needle or other instrument within the lesion).

Ill. INDICATIONS/CONTRAINDICATIONS

Advantages of percutaneous sampling procedures include reducing the number of diagnostic surgical procedures by substituting procedures that have less or possibly equal morbidity and/or equal accuracy and are less costly.

Indications for percutaneous US-guided breast procedures include, but are not limited to, the following.

A. Cysts and cystic masses

1. **Masses that do not fulfill the US criteria for simple cysts;**
2. **Cysts that are symptomatic;**
3. **Cysts where documentation of evacuation is desirable;**
4. **Cysts where imaging guidance would help avoid complications;**
5. **Suspected abscesses or infected cysts for diagnostic aspiration and drainage;**

B. Solid masses

Percutaneous tissue sampling can be performed for:

1. **A mass that is thought to be highly suggestive of malignancy (Breast Imaging Reporting and Data System, BI-RADS™ Category 5), to confirm the diagnosis so that definitive treatment options can be selected in advance;**
2. **Multiple suspicious or indeterminate masses, particularly in a multicentric distribution (two or more different quadrants), to facilitate treatment planning;**
3. **Suspicious masses (BI-RADS™ Category 4);**
4. **Probably benign masses (BI-RADS™ Category 3) where patient anxiety is high or the procedure is requested for confirmation;**

C. Lesions where the initial FNA or CNB procedure or the surgical biopsy has provided insufficient material for analysis. Percutaneous sampling or surgical excision are alternatives for repeat biopsy.

D. Presurgical localizations

For solid masses, US-guided localization may be performed when the lesion is identifiable with US:

1. **If surgical excision is planned; or**
2. **If a previously sampled mass receives a histopathologically based recommendation for complete excision; or**
3. **If there is discordance between the mammographic and the US-based level of suspicion and the histopathologic interpretation of a previously sampled mass**

There are no absolute contraindications to percutaneous procedures. Prior to the procedure, the patient should be asked about allergies, use of medications such as aspirin, anticoagulants, or a history of bleeding diatheses. As with all interventional procedures, the procedure should be fully described and the relative risks, limitations, benefits, and alternatives should be explained to the patient.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Physicians should meet the initial qualifications specified in the ACR Standards for Screening Mammography and Diagnostic and Problem-Solving Mammography. In addition, and in accordance with the ACR Standard for Performing and Interpreting Diagnostic US Examinations, these physicians should have a thorough understanding of the indications for US examinations as well as a familiarity with the basic physical principles and limitations of the instrumentation and technology of US imaging. They should be capable of correlating the results of mammographic and other examinations and procedures with sonographic findings. Physicians responsible for breast US examinations and procedures should be able to demonstrate familiarity with US breast anatomy. These physicians should provide evidence of training and requisite competence by meeting the following criteria:

1. **Completion of an approved residency which includes 3 or more months of dedicated formal diagnostic US training, including breast ultrasound, under the supervision of qualified individual(s) as defined in this document and with formal interpretations of those studies performed. In addition, the physician should have successfully passed written and oral board certification examinations including sections pertaining to diagnostic US. This training should include sufficient experience in image-guided interventional procedures including indications for these procedures, knowledge of complications that might be incurred, and techniques for successful completion of these procedures.**

or

2. **If residency training did not include US, appropriate fellowship or postgraduate training during which the physician should have been involved with the performance and interpretation of at least 500 ultrasound examinations which should include a broad spectrum of ultrasound uses, including breast ultrasound. This should be under the direct supervision of a qualified physician. A qualified physician is one who meets the criteria defined in this document. This training should include sufficient experience in image-guided interventional procedures including indications for these procedures, knowledge of complications that might be incurred, and techniques for successful completion of these procedures.**

or

3. **In the absence of residency training, formal fellowship or post-graduate education, documentation of clinical experience could be acceptable providing it can be**

established that the physician has had at least two years of ultrasound experience during which a minimum of 500 general or 100 breast ultrasound examinations were performed and formally interpreted. This training should include sufficient experience in image guided interventional procedures including indications for these procedures, knowledge of complications that might be incurred, and techniques for successful completion of these procedures.

Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada; or an equivalent body that certifies in this discipline and is recognized by the American Board of Medical Specialties (ABMS) may be considered proof of adequate physician qualification. However, the physician's residency and/or fellowship training must include specific criteria for training as outlined in 1.

Maintenance of competence in the performance of breast ultrasound interventional procedures requires continuing clinical activity including:

1. **Regular performance and interpretation of breast ultrasonographic examinations that meet the guidelines of the ACR Standard for Performing of the Breast Ultrasound Examination.**
2. **Documented performance of at least 12 percutaneous US-guided breast interventional procedures per year.**
3. **Continuing education that should be in accordance with the ACR Standard for Continuing Medical Education (CME)**

V. SPECIFICATIONS OF THE EXAMINATION

The decision to perform an interventional procedure should be in conformity with the general principles noted in the Section 11 above. A full US examination of the mass or area of the breast in which the procedure is planned should be completed.

Benefits, limitations, and risks of the procedure as well as alternative procedures should be discussed with the patient. Informed consent should be obtained and documented.

There should be conformity with standards of sterility or cleanliness in the preparation of the breast, and the field in which the procedure is to be performed, and the probe housing and transducer face to minimize risk of infection.

Using a high frequency transducer, continuous visualization of the needle path is possible. Depending on the probe configuration, the geometry of the acoustic beam, and the route of needle entry, either a small portion of the needle may be visible as an echogenic dot, or preferentially, if the needle entry is in alignment with the acoustic beam, the entire shaft of the needle including its tip may be visible. Documentation of appropriate needle positioning for sampling should be obtained as part of a medical record.

To minimize hematoma formation, the skin entry site and region of needle sampling should be compressed between needle passes, if multiple passes are made to sample a lesion. Coaxial techniques may also be used with US, FNA, and CNB. Effective techniques to achieve hemostasis should be used.

The physician who performs the procedure should be responsible for obtaining results of the cytologic or histologic sampling, and these results should be communicated to the referring physician or to the patient, as appropriate. These communications should be documented.

VI. DOCUMENTATION

A permanent record of interventional procedures should be documented on a retrievable image storage format. Where appropriate, correlative mammography should be performed in conjunction with the procedures.

A. Imaging labeling should include permanent identification containing:

1. **facility name and location**
2. **examination date**
3. **patient's first and last names**
4. **identification number and/or date of birth**
5. **designation of the left or right breast**
6. **location of the lesion in**

B. The physician's report of US-guided needle procedures of the breast should include:

I. **procedure undertaken and its purpose**
2. **local anesthesia, if used, and amount**
3. **designation of the left or right breast**
4. **location of the lesion in the breast using diagrammatic, clock, or other consistent notation**
5. **immediate complications and treatment, if any**
6. **specimen radiographs or monograms, if performed, and results**
7. **post-procedure mammograms and/or monograms, if obtained**

C. Follow-up documentation:

1. **delayed complications and required treatment, if any**
2. **pathology results, if any**
3. **record of communications with patient and referring physician**
4. **patient disposition based on tissue sampling results and imaging information**

D. Retention of the procedure's images including those of the specimen should be consistent with the policies for retention of mammograms and breast sonograms in compliance with federal and state regulations, local health care facility procedures, and with clinical need.

E. Reporting should be in accordance with the ACR Standard for Communication.

VII. EQUIPMENT SPECIFICATIONS

High resolution linear array transducers are preferred for breast US examinations and percutaneous procedures. The transducers should be operated at the highest clinically appropriate frequency, realizing that there is a trade off between resolution and beam penetration. Ordinarily, transducer frequencies of 7 to 10 MHz are used for breast imaging and interventional procedures. All equipment should be in accordance with the guidelines described in the ACR Standard for Performing the Breast Ultrasound Examination.

VIll. EQUIPMENT QUALITY CONTROL

Each facility should have documented policies and procedures for monitoring and evaluating the effective management, safety, and proper performance of imaging and interventional equipment. The quality control program should be designed to maximize the quality of the diagnostic information. Equipment performance should be monitored in conformity with standards for ultrasound imaging and phantom testing for resolution. This may be accomplished as part of a routine preventative maintenance program.

IX. QUALITY IMPROVEMENT

Results of US-guided and other image-guided percutaneous breast interventional procedures should be monitored on a continuous basis. Records should be kept of the cytologic and histologic interpretation associated with presurgical localizations of nonpalpable lesions, fine-needle biopsies and aspirates, core-needle biopsies, and atypical cyst aspirates.

The number of cancers diagnosed and the number of complications requiring treatment should be documented. Also to be recorded are the numbers of inconclusive results, inadequate samples, recommendations for complete excision of a lesion for more accurate histopathologic diagnosis, and other indications for repeat percutaneous or excisional biopsies recommended following US-guided FNA or CNB.

It is desirable that imaging findings and pathologic interpretations be correlated in every instance and that formal provision for review of these findings be made.

The rate of compliance with recommended followup in women with benign histopathologic or cytologic interpretations following sampling of lesions thought most likely to be benign should be tracked. Follow-up of all biopsies should be pursued to detect and record any false-negative and false-positive results.

References:

Parker, SH, Jobe WE, Dennis MA, et al. US-guided automated large-core breast biopsy. Radiology 1993; 187:507-511.

American College of Radiology Standards, 1997